

END TO END CONTAMINATION CONTROL

AUTOMATED HOT CELL DECONTAMINATION WITH HYDROGEN PEROXIDE VAPOR

Validated and compliant surface bio-decontamination with 35% Hydrogen Peroxide Vapor technology utilizing **REGISTERED HYDROGEN PEROXIDE STERILANT**

For our filling cell family, we have the option for full automatic decontamination of multiple enclosures using Hydrogen Peroxide Vapor (HPV). Our shielded isolators and their adjacent compartments provide a controlled aseptic environment. To minimize the risk of decontamination, a validated sterilization cycle is essential.

Cycle development

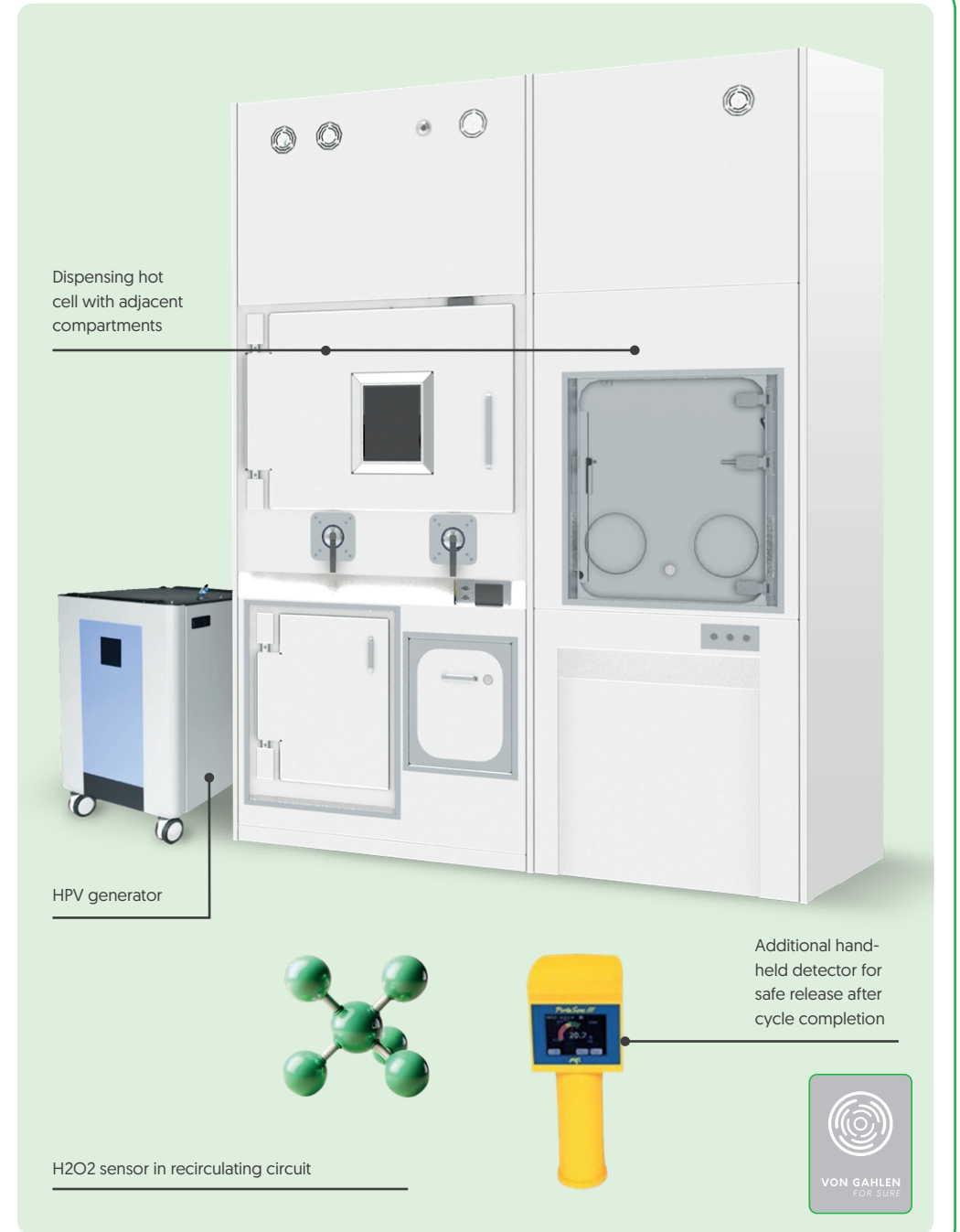
- The decontamination cycle/process with the basic steps as described is completely developed in accordance with the hot cells and depending on your requirements.
- With this unique cycle development comes a fully compliant decontamination process
- This process is repeated every cycle, so the decontamination time is always as expected in combination with successful decontamination.

The HPV process is tested and validated with a 6-log sterility assurance level. Standard cycles are available for the following compartment combinations: Filling the hot cell main compartment (including adjacent compartments such as the waste and product retrieval port) in or excluding the preparation box. This off-the-shelf solution saves lead time and cost.

On request, HPV decontamination can also be integrated into other Von Gahlen hot cell types.

PRO'S OF DECONTAMINATION WITH HPV

- Unmatched level of effectiveness spanning every exposed surface of an enclosed area.
- The HPV will convert into water vapor and oxygen, leaving no residue.
- Swift decontamination cycles. A full 6-log reduction for the whole system [Dispensing hot cell + Preparation box + Waste + Product Retrieval Port] combined will take approximately 2.5 hours for a closed system with a catalytic aeration unit. When the HPV can additionally be extracted through the HVAC (with or without a catalytic filter), this time will be even shorter, significantly reducing downtime and increasing operational efficiency.



STANDARD FEATURES

THE PROCESS EXPLAINED

Safety first:

- A hot cell isolator with a decontamination loop is checked for leakage by performing a leak test. After a successful result; the next phases can start.

Conditioning Phase

- The bio-decontamination system warms up, getting ready to disperse the vapor. You do not need to reach or wait for temperature or humidity levels to begin.

Vaporization

- The decontamination system emits the vapor into the enclosed area and fills the space, pushing the vapor against exposed surfaces, including surrounding complex shapes and crevices.

Dwell Phase

- With the vaporization now complete, the enclosed area is at a standstill, allowing the peroxide to dwell on every exposed surface and help kill microorganisms.

Aeration

- Your HVAC system, in combination with the hot cell extraction and the high-powered aeration units, uses catalytic conversion to effectively remove the hydrogen peroxide vapor from the enclosed area. The vapor is converted into water vapor and oxygen.



System operation/ control

- Operating bio-decontamination system, a user-friendly, intuitive interface is provided.
- The physical location of the main unit can be inside the cleanroom or in a technical area. The system can be controlled remotely from either location.
- Connective capability for inclusion into more complex systems; Modbus TCP/IP or volt-free contacts and remote start/stop for integration, automation, and data capture.
- Software is based on a recipe, which is your specific decontamination cycle.
- The data of each batch is logged and stored in the database. Reports can be printed or used paperless.
- Audit Trail, in accordance with risk management principles, captures general system events as well as any activities relating to the acquisition, deletion, overwriting, and changes to data for audit purposes.
- Implementation of software is conformed to SDLC [software development life cycle].
- Development and validation of software according to GAMP and is technically compliant with Eudralex V4 Annex 11 and 21 CFR Part 11.

Injection method

- The hydrogen peroxide vapor is injected directly into the main compartment through a fixed nozzle, resulting in maximum effectiveness. The advantage of injecting the HPV below the downflow filter instead of via the air inlet of the hot cell is a much faster cycle time. This is achieved by not oversaturating the downflow filter.

OPTIONAL FEATURES

- Cart type external additional catalytic aeration unit to speed up the decomposition.
- Fixed additional catalytic aeration unit built into the HVAC to speed up the decomposition.
- Combination of both catalytic aeration units for the highest conversion speed.



CONSUMABLES

- Registered Hydrogen Peroxide Sterilant: EPA Registration Number: 72372-1-86703.
- Biological indicator set.

